

Docket No. ECV-4652CIPDIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

5 In re application of: Carpentier, et al. ) Group Art Unit: 1744  
Application No.: 09/283,596 )  
Filed: April 10, 1999 )  
10 For: APPARATUSES FOR TREATING BIOLOGICAL )  
TISSUE TO MITIGATE CALCIFICATION )

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15 PROPOSAL FOR 11/15/00, 2:00 PM INTERVIEW, DO NOT ENTERAMENDMENT AFTER FINAL UNDER 37 CFR §1.116

20 Commissioner of Patents  
Washington, D.C. 20231

Dear Sir:

Responsive to the FINAL Office Action dated October 6, 2000, please make the following changes to the above-referenced application.

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IN THE CLAIMS:

Please amend the following claims:

1. (Twice Amended) An apparatus for treating at least partially fixed biological tissue to inhibit calcification of the tissue following implantation in a mammalian body, comprising:  
30 a flow container;  
a supply of treatment fluid comprising a reservoir;  
a fluid input to the container;  
a fluid output from the container;  
a tissue mount for positioning the at least partially fixed biological tissue within the container between the input and output and restrain its gross movement therein; and  
35 means for heating the fluid to a temperature greater than body temperature (>37°C)  
comprising a heater for heating fluid in the reservoir.

Please cancel claim 7.

40 In claim 8, line 1, replace "claim 7" with --claim 1--.

Application No.: 09/283,596

Filed: April 10, 1999

10. (Twice Amended) An apparatus for treating at least partially fixed biological tissue to inhibit calcification of the tissue following implantation in a mammalian body, comprising:

5 a piece of at least partially fixed biological tissue;

a container suitable for containing tissue treatment fluid and immersing the piece of at least partially fixed biological tissue in the fluid;

a shaker for causing treatment fluid movement within the container; [and]

means for heating the treatment fluid and tissue within the container; and

10 means for restraining the immersed tissue from gross movement within the container.

13. (Twice Amended) An apparatus for treating at least partially fixed biological tissue to inhibit calcification of the tissue following implantation in a mammalian body, comprising:

15 a piece of at least partially fixed biological tissue;

a container suitable for containing tissue treatment fluid and immersing the piece of at least partially fixed biological tissue in the fluid;

means for causing treatment fluid movement within the container comprising a stirrer immersed in the treatment fluid; [and]

20 means for heating the treatment fluid; and

means for restraining the immersed tissue from gross movement within the container.

Please cancel claim 17.

In claim 18, line 1, replace "claim 17" with --claim 13--.

Application No.: 09/283,596  
Filed: April 10, 1999

25. (Twice Amended) An apparatus for treating an at least partially fixed sheet of biological tissue to inhibit calcification of the tissue following implantation in a mammalian body, comprising:

5 a container suitable for containing tissue treatment fluid having a fluid input and a fluid output;

a system for continuously flowing treatment fluid through the flow container between the input and output;

10 a tissue mount for positioning the at least partially fixed sheet of biological tissue within the container between the input and output and restrain its gross movement therein, the tissue mount being adapted to mount the tissue sheet in a planar configuration substantially parallel to the direction of flow of the treatment fluid, the sheet of biological tissue being immersed in the continuous flow of treatment fluid; and

means for heating the treatment fluid.

15 Please cancel claim 40 without prejudice.

#### REMARKS

Claims 1-25 and 28-42 were pending prior to the present Office Action. With this amendment, claims 7, 17, and 40 are canceled, therefore claims 1-6, 8-16, 18-25, 28-39, and 41-42 are presently 20 pending.

Claims 10, 11, 13-16, 20, 21, and 23 stand rejected under 35 USC §102(b) in view of Fisher. In response, Applicants have amended claims 10 and 13. Allowable claim 17 has now been combined with claim 13 and canceled, and **therefore claims 13-16 and 18-24 are believed allowable**.

25 Claim 10 has been amended to incorporate what is believed patentable subject matter based on the disposition of allowable claim 13 (as amended). That is, claim 13 now specifies that the apparatus for treating tissue further includes means for restraining the immersed tissue from gross movement within the container. Claim 10 thus differs from allowable claim 13 only in that the means for

Application No.: 09/283,596

Filed: April 10, 1999

causing treatment fluid movement within the container is a shaker, and not a stirrer. As Fisher does not disclose a shaker, let alone a means for restraining the immersed tissue, claims 10-12 are also believed allowable thereover.

Claims 10, 11 and 12 stand rejected under 35 USC §102(b) in view of Freedman. In response, 5 Applicants have amended claim 10 as indicated above. Freedman does not disclose a means for restraining the immersed tissue from gross movement within the container, and **thus claims 10-12 are believed allowable.**

Claims 1, 4, 7, 8, 25, 30, 31, and 40 stand newly rejected under 35 USC §102(e) in view of Park, et al.. Park, et al. disclose both static and dynamic tissue culturing systems, with the static system 10 shown in Figs. 4-5. The system includes a mesh on which tissue to be cultured is "placed" in an incubation chamber. The tissue is then contacted alternately with a fluid culture medium and an oxygen-containing gas, with the former being periodically delivered by a peristaltic pump from above the mesh. The fluid medium "runs down" the space between the mesh and the chamber wall in which the tissue is positioned.

15 Claim 1 has been amended to specify that the apparatus includes a reservoir for the treatment fluid and a heater for heating fluid in the reservoir. Although Park, et al. disclose a reservoir, there is no disclosure or suggestion of heating the fluid within the reservoir. Instead, the only disclosure of heating provides that the incubation chamber is maintained at a constant temperature (either 37°C or 38°C) (**emphasis added**). **Therefore, claims 1-6 and 8-9 are believed allowable.**

20 Claim 25 has been amended to specify that the apparatus includes a system for continuously flowing treatment fluid through the container and that the tissue mount positions the immersed sheet of biological tissue in a planar configuration substantially parallel to the direction of flow of the treatment fluid. There is no disclosure or suggestion of providing continuous flow or immersing the tissue in a continuous flow stream. Indeed, Park, et al. teach against continuous fluid flow to ensure 25 sufficient oxygen is supplied to the tissue (see, e.g., column 1, third full paragraph). Further, although Park, et al. disclose spacing pieces of tissue in series parallel to the direction that the fluid travels (down, by gravity), there is no disclosure of providing a tissue mount adapted to immerse a tissue

Application No.: 09/283,596

Filed: April 10, 1999

sheet in a planar configuration substantially parallel to the direction of continuous flow of the treatment fluid. **Therefore, claims 25 and 28-31 are believed allowable.**

Claims 32-39 and 41-42 are allowed, and claim 40 has been canceled.

In summary, claims 1-6, 8-16, 18-25, 28-39, and 41-42 are believed allowable over the prior art 5 of record. If there is any further hindrance to allowance, the Examiner is encouraged to contact the undersigned by telephone.

Respectfully submitted,

Date: \_\_\_\_\_

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Guy Cumberbatch  
Registration No. 36,114  
Stout, Uxa, Buyan & Mullins  
Telephone: (949) 450-1750 (MWF)  
c/o Edwards Lifesciences LLC  
One Edwards Way  
Irvine, California 92614  
Telephone: (949) 250-6807 (TTh)  
Facsimile: (949) 250-6850

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